PATENT

Case No. 8627/096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	Art Unit: 3751
Fred T. Parker	)	
	)	Examiner: A. Ramana
Serial No.: 09/815,567	)	
	)	
Filed: March 23, 2001	)	
	)	
For: INTRODUCER SHEATH	)	
	)	

RULE 1.132 DECLARATION

I, David Barnes, declare as follows:

1. I am over 18 years of age and competent to make this Declaration.

2. I graduated from the University of Pittsburgh in 1984 with a Bachelor's in Engineering degree and a major in Mechanical Engineering.

3. Since 1999, I have been employed by ABAQUS Central, Inc., of West Lafayette, Indiana. In 2004, I was promoted to General Manager of the ABAQUS Central office. In this position, I supervise the ABAQUS Central Office, consisting of 18 employees. Prior to my promotion, I was Engineering Services Manager for two years.

4. Prior to joining ABAQUS Central, I was employed by Continental Design Company of Anderson, Indiana for a period of 8 years.

5. Prior to joining Continental Design Company, I was employed by Allison Gas Turbine, a division of General Motors Corporation, in the Advanced Engine Design department where I was responsible for the Finite Element Analysis ("FEA") of military and civilian aircraft turbine engine components.

6. The primary business of ABAQUS Central is sales, support, and for-fee consulting using the ABAQUS computer program. ABAQUS program performs Finite

Element Analysis. FEA allows engineers to simulate the physical behavior of engineered products using a computer. FEA further allows engineers to minimize the number of physical prototype tests performed during development of their products. FEA further allows engineers to gain deeper understanding into the physics of their products than can be gained by physical testing alone. The ABAQUS program is commonly used in many industries. Particularly in the medical industry, the ABAQUS program is commonly used to simulate stents, catheters, and other interventional medical devices.

7. I have been asked by Cook Incorporated, ("Cook") of Bloomington, Indiana, to examine Cook's United States Patent Application Serial No. 09/815,567 ("the '567 application"), the prosecution history of the '567 application, and the prior art references cited by the Examiner during the prosecution of the '567 application.

8. The '567 application describes a flexible, kink-resistant introducer sheath. It is highly desirable that an introducer sheath be flexible and resistant to kinking. These properties enable the sheath to be readily advanced through tortuous body passageways and/or directed to sensitive treatment sites. As the sheath is advanced through these body passageways, it is also desirable that the sheath maintain its generally circular cross-section through as large a bending angle as possible. This property allows for the passage of a medical interventional device, such as a stent, through the generally circular cross-section of the sheath for delivery to a selected site of the body passageway. It is also desirable that the sheath have as thin-walled a construction as possible. This property enables the medical practitioner to make as small an opening in the body for percutaneous entry as possible, and to pass the sheath through as small diameter body passageway as possible.

9. The '567 application includes two independent claims, namely claims 1 and 21, each directed to a flexible, kink-resistant introducer sheath. Claim 1 is representative:

> Claim 1. A flexible, kink-resistant introducer sheath comprising:
> an inner tube extending to a distal end;
> a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end;
> a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends distally therebeyond; and

at least a second outer tube disposed around said wire coil and said inner tube therewithin extending distally from said first outer tube distal end and covering said distal end portion of said wire coil and extending slightly beyond said distal end of said inner tube,

said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a substantially softer durometer than said material of said first outer tube.

10. The Examiner rejected claim 1 under 35 U.S.C. 103(a) over U.S. Patent No. 5,792,124 to Horrigan, et al ("Horrigan") in view of a secondary reference to Park, et al. ("Park"). As best illustrated in Fig. 3, Horrigan is directed to a reinforced catheter having a lubricous inner liner 40; a wire braid reinforcement 35; a first outer tube 15; and a second outer tube 20. The second outer tube is made of a softer material than the first outer tube. According to the Patent Examiner in the Final Office Action mailed June 29, 2004 ("Final Action"), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan with a "braided wire coil" as disclosed by Park. According to the Examiner, "The sheath of the combination of Horrigan et al and Park et al is inherently kink resistant due to the presence of reinforcement in the form of a braided wire coil and inherently flexible since it is made of polymer." Final Action, page 3.

11. In the Final Action, the Examiner also took issue with the Applicant's contention that there are numerous significant differences between a braid-reinforced sheath and a coil-reinforced sheath, and in particular, that a braided sheath provides inferior kink resistance when compared to a coiled sheath. As stated by the Examiner:: "The Examiner disagrees with Applicant's position that a braid-reinforced sheath is prone to kinking while a coil-reinforced sheath is effective for resisting kinking." Final Action, page 6.

12. I have been asked by Cook to construct a computer FEA model of a braid-reinforced catheter constructed according to the teachings of Horrigan, cited by the Examiner as the closest prior art of record. For purposes of comparison, I have also been asked to construct a computer FEA model of another reinforced catheter constructed according to the teachings of Horrigan and identical to the braid-reinforced catheter, except that the reinforcement has been modified to comprise a coil. I have also been asked to construct a third computer FEA model of a catheter constructed according to the teachings of Horrigan

that is identical to the braid- and coil-reinforced catheters, except that no reinforcement was included in this catheter model.

13. In all three models, the sheath was constructed from two layers of polymeric material. The inner layer was made from TEFLON® with an inner diameter ("ID") of 2.50 mm (7.5 fr), and outer diameter ("OD") of 2.80 mm and an elastic modulus of 460 MPa. The outer layer was made from PEBAX® with an ID of 2.80 mm, an OD of 3.10 mm, and an elastic modulus of 414 MPa. In the braid-reinforced model, the braid was represented by an 8-wire braid construction with braid wires with a circular cross section of diameter 0.07 mm made from steel with a modulus of 200000 MPa. The braid wires made an angle of 55 degrees with the longitudinal axis. In the coil-reinforced model, the coil was represented by a rectangular cross section steel wire with a width of 0.3048 mm and a thickness of 0.0762 mm. The coil made an angle of 86 degrees with the longitudinal axis. In the FEA models, a commonly-used smeared equivalent modeling approach was used to include the additional stiffness of the braid- and coil-reinforcements in the two-layer tube model.

14. The above parameters were chosen to be well within the teaching of the Horrigan patent and are broadly representative of the type of physical embodiment familiar to one of ordinary skill in the art.

15. Each of the three models that I constructed according to the teachings of the Horrigan patent (un-reinforced two-layer sheath, braid-reinforced two-layer sheath, and coil-reinforced two-layer sheath) had the same two-layer construction, the only difference being the nature of the reinforcement, or in the case of the unreinforced model, the absence of a reinforcement.

16. Following the construction of the computer FEA models of the three sheaths, each model was then bent to progressively larger bend angles to simulate the behavior of the sheaths to severe bending. The three simulation results were compared in many different ways as discussed in the following paragraphs.

17. First, the displacement behavior of the braid-reinforced and coil-reinforced sheaths were compared when bent to the same total bend angle of about 45 degrees per 10 mm length sheath segment. These results are attached hereto as Exhibit A. Exhibit A shows the deformed configuration of the braid- and coil-reinforced sheath FEA models at equal bend angles that correspond to wrapping the tube around a cylinder of about 1 inch diameter.

In Exhibit A, the braid-reinforced sheath is indicated at the right of the page and the coil-reinforced sheath is indicated at the left. As illustrated, the coil-reinforced sheath has not kinked at this angle whereas the braid-reinforced sheath has kinked severely.

18. A second way to compare the behavior of the bent sheath models was to compare the resistance to bending of the three sheath models described above as the bending angle increases. Results of this examination are attached hereto as Exhibit B, which represents an X-Y plot of bending moment vs. radius of curvature. The term "bending moment" refers to the amount of bending "force", or more accurately stated, bending "moment", that one would feel in his hands if he tried to bend the sheath. The radius of curvature corresponds to the amount of bending in the sheath (as if to wrap the sheath around a cylinder) to form a full circle. When the tube finally kinks, the force will drop quickly as the cross-section collapses. This may perhaps best be understood by considering the behavior exhibited by a plastic drinking straw when it is bent to the point where the cross-section of the bent straw collapses and kinks. As the kink occurs in the bent straw, the straw becomes very flexible and the bending moment decreases substantially. The amount of bending at which this moment decrease occurs correlates with the point at which a kink forms in the cross-section. As shown in the plot of Exhibit B, the un-reinforced sheath kinks at a radius of curvature of about 29 mm, and the braid-reinforced sheath kinks at a radius of curvature of about 15 mm. The coil-reinforced sheath does not kink until it reaches a radius of curvature of about 11 mm. A difference of this magnitude in the radius of curvature needed to form a kink is significant, particularly to the medical practitioner who desires to pass a further medical device, such as a stent, through the interior of the sheath.

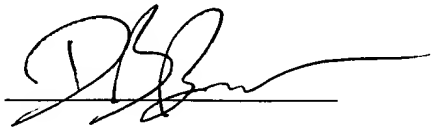
19. A third way to compare the behavior of the bent sheath models was to compare the relationship in the minor-to-major diameter ratio of the cross-section in the three sheath models as they are bent. The results of this test are provided as Exhibit C. A diameter ratio of 1.0 means the cross-section is circular (both diameters are the same), while a diameter ratio of 0.0 means the cross section has totally collapsed and the opposing walls of the minor diameter are touching each other. These plots show that the cross section collapses rapidly as the sheaths kink at the radii of curvature described above. This plot also shows that the coil-reinforced cross-section maintains the "most circular" cross-section of all three types with a diameter ratio closest to 1.0. Furthermore, the plots also show that the coil-

reinforced sheath maintains a more constant cross-sectional ratio of around 0.9 over a wider bend angle range than the other two. In particular, even before kinking occurs in the braid-reinforced tube, the diameter ratio has decreased to nearly 0.6, while the coil-reinforced tube maintains a value closer to 0.8 before kinking. The ability of a sheath to maintain a substantially circular cross-section is essential if an interventional device, such as a stent, is to be passed through the sheath for delivery into a body passageway.

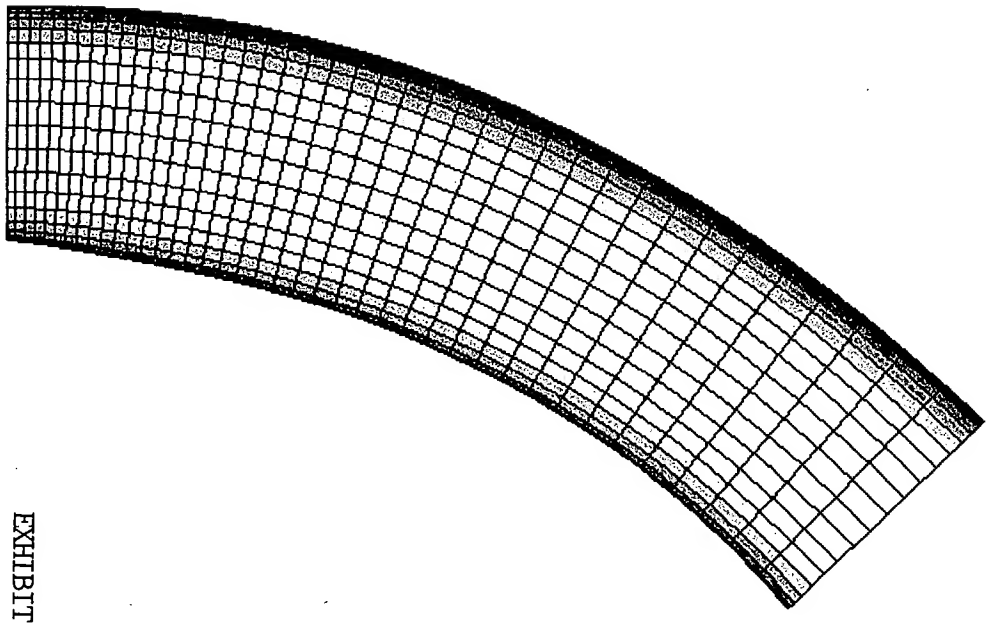
20. Based upon the foregoing, I have concluded that there are two major advantages of a coil-reinforced sheath over a braid-reinforced sheath under the conditions of my simulations. The first advantage is that the coil-reinforced sheath has a preferential stiffening effect in the circumferential direction as opposed to the axial direction. Since cross-sectional kinking is related to the ratio of circumferential stiffness (that opposes kinking) to the axial compressive stress (that causes kinking), a preferential increase of circumferential stiffness is desirable. Stated another way, the resistance of the cross section to kinking is increased by the coil without a corresponding increase in the compressive stress at the bent inner diameter of the sheath during bending – low axial compression increase with greater circumferential stiffness increase leads to increased kink resistance. In a braid-reinforced sheath, the circumferential stiffening is accompanied by a corresponding increase in axial compressive stress. Thus, while the braid-reinforced sheath does provide improved kink resistance compared to the un-reinforced sheath, the kink resistance is limited when compared to that of the coil-reinforced sheath.

21. The second advantage is that a coil, at any helix angle, always has base material between its coils. This can be noted by visual inspection of a coil-reinforced sheath. In effect, the only way for load to be transmitted axially in a coil is through the polymeric material of the tubes that fills the space between the turns in the coil. The same is not true in a braid where the crossing braid wires provide a load path axially down the sheath. This is why the braid produces additional axial compressive stress whereas the coil does not.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed by me on May 25, 2005, at West Lafayette, Indiana.



Coil Model at 45 deg bend angle



Braid Model at 45 deg bend angle

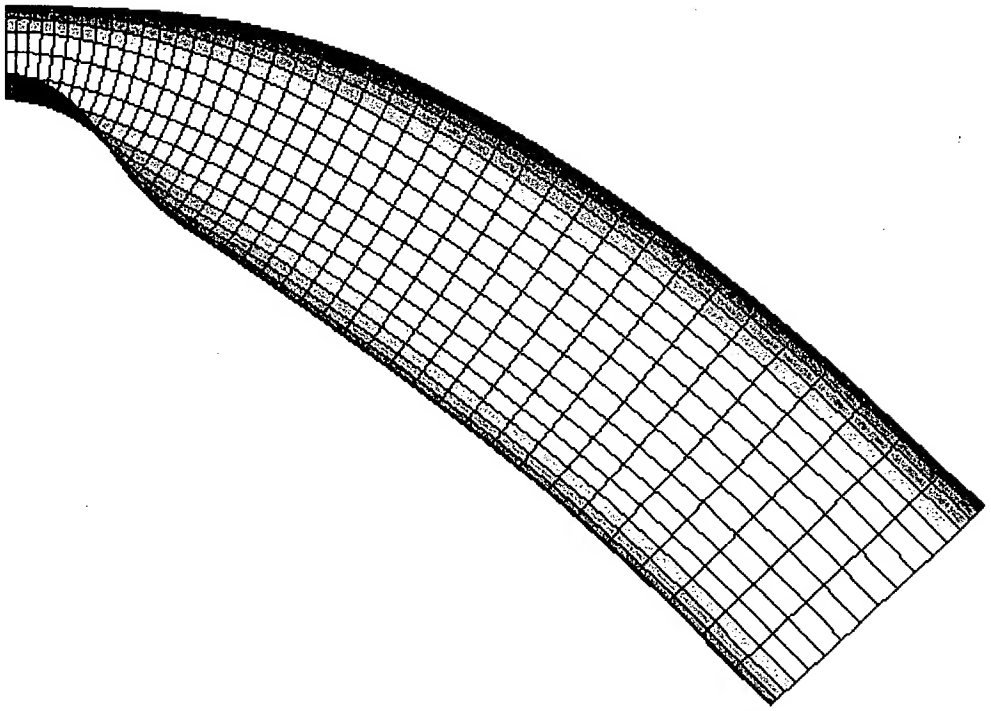
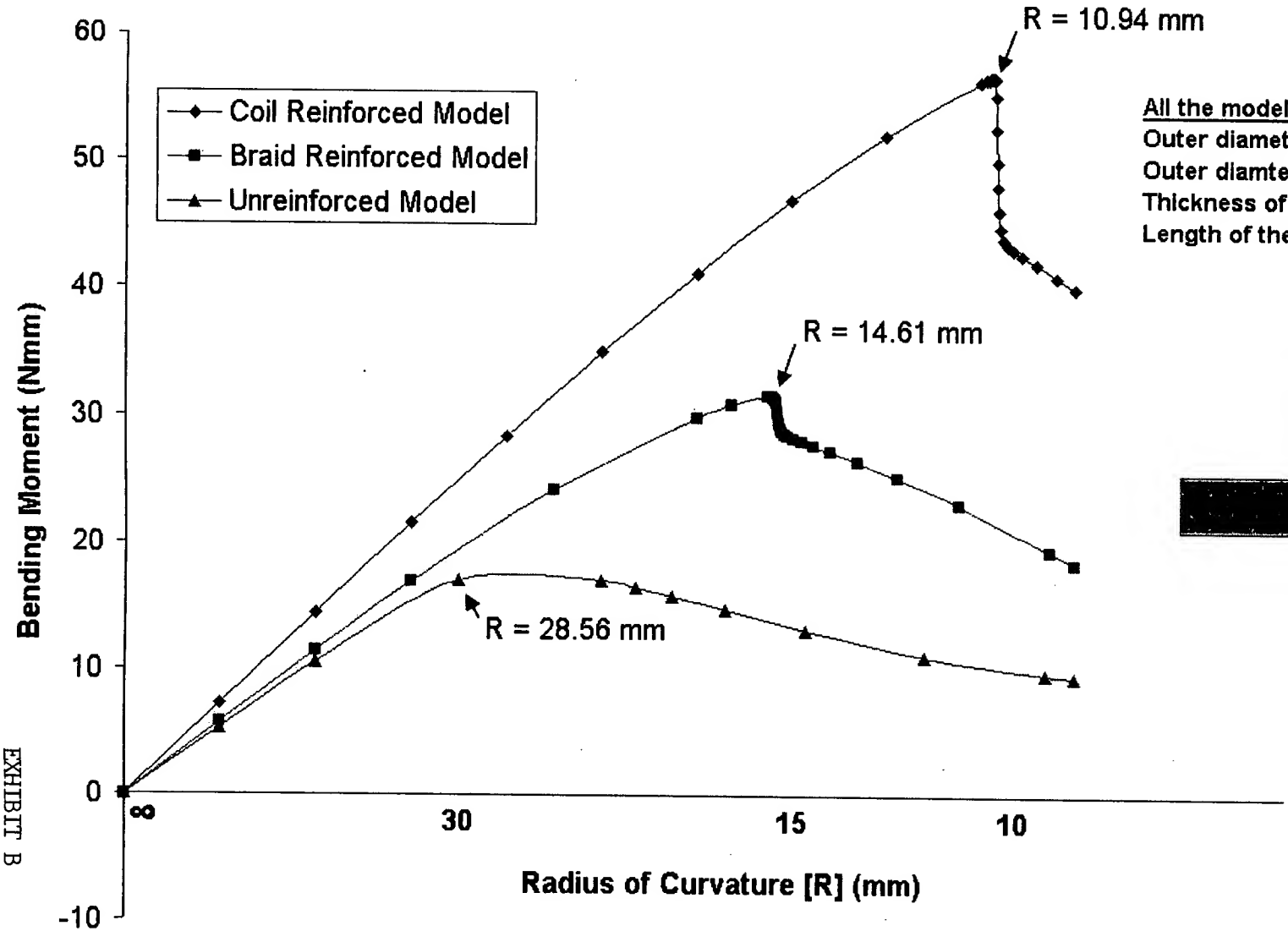


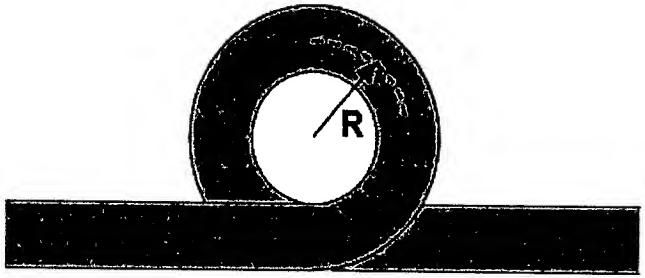
EXHIBIT A

Bending Moment Comparison



All the models have identical tubing dimensions:

Outer diameter of Inner tube	: 2.80 mm
Outer diamter of outer tube	: 3.10 mm
Thickness of the tubes	: 0.15 mm
Length of the tubes	: 10.00 mm



R= Radius of Curvature

EXHIBIT B

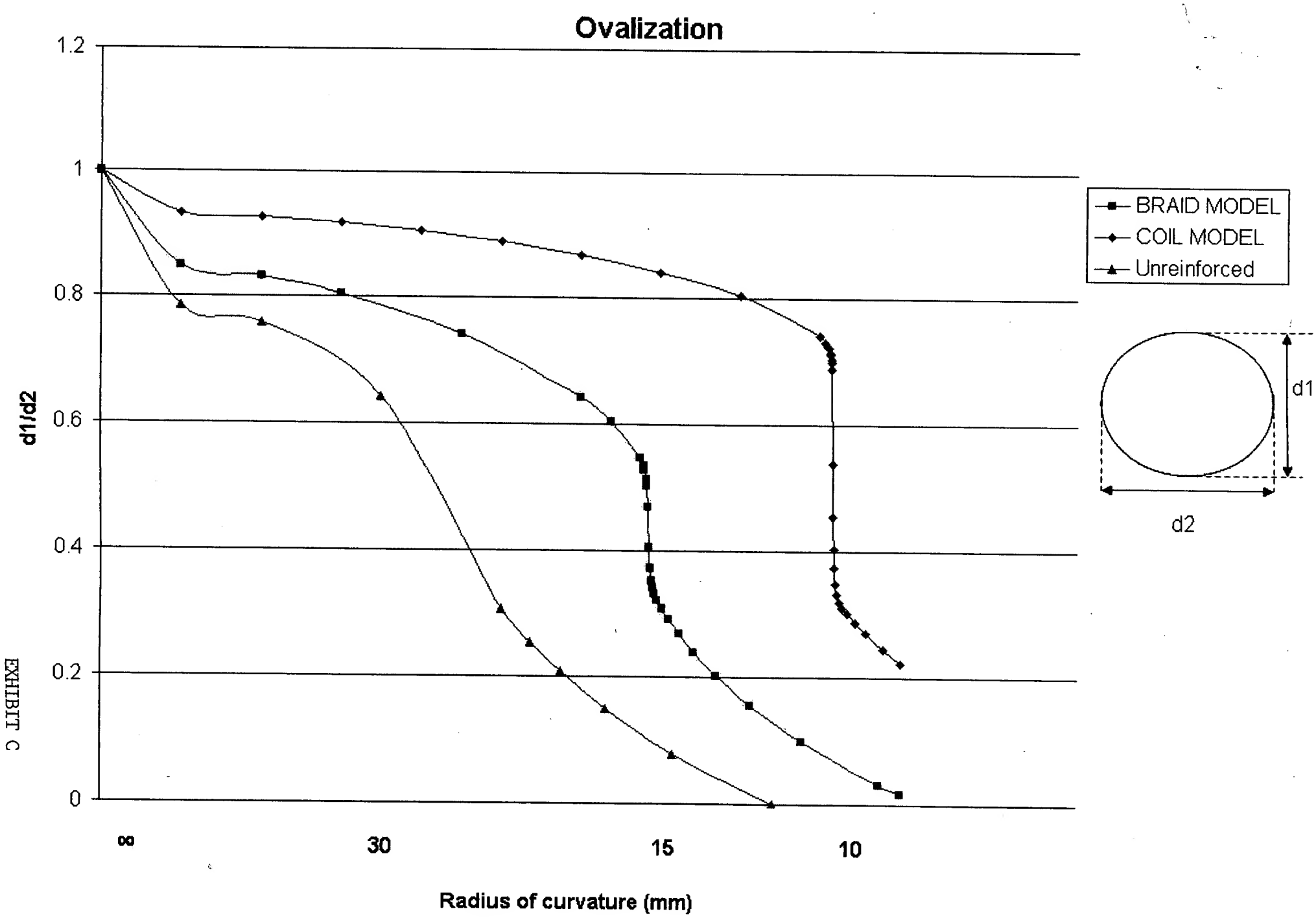

Ovalization
1.2
1
0.8
0.6
0.4
0.2
0
d1/d2
∞
30
15
10
Radius of curvature (mm)
BRAID MODEL
COIL MODEL
Unreinforced
d1
d2

EXHIBIT C

PATENT

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	)	Art Unit: 3751
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Serial No.: 09/815,567	)	
	)	
Filed: March 23, 2001	)	
	)	
For: INTRODUCER SHEATH	)	
	)	

DECLARATION

I, Gary Roubin, M.D., Ph.D., declare as follows:

1. I am over 18 years of age and competent to make this Declaration.

2. I am a medical doctor and serve as the Chairman of the Department of Interventional Cardiology at Lennox Hill Hospital in New York. My qualifications are further described in the attached curriculum vitae.

3. During the course of my medical practice involving endovascular treatments, it is frequently necessary to utilize guiding catheters or guiding sheaths for purposes such as the delivery of stents and related devices into various areas of the peripheral vasculature. Utilizing technology in common use prior to about 1994, it was generally difficult to advance a guiding catheter or sheath through challenging peripheral vascular anatomy such as distal common carotid arteries, tortuous iliac arteries, and around the aortic bifurcation. Existing guiding catheters and sheaths in use at the time generally included either a layered structure having a braided reinforcement, or were unreinforced.

4. Around 1994, I began using a guiding sheath developed by Cook Incorporated, of Bloomington, Indiana. This guiding sheath differed from previous braid reinforced guiding catheters and unreinforced sheaths in that it comprised a layered structure

having a low friction inner layer, a coiled reinforcement fitted around the inner layer, and an outer nylon layer positioned around the coil and inner layer and connected to the inner layer through the spaces of the coil.

5. With the use of this coiled-reinforced sheath as opposed to a braid-reinforced guiding catheter, the coil-reinforced sheath was found to have greater flexibility and kink-resistance than the braid-reinforced device. This beneficial property proved essential in negotiating tortuous peripheral vasculature. For example, prior to the use of a coil-reinforced sheath as described, the guiding catheter could not be reliably advanced into the distal common carotid artery and cerebral anatomy. Instead, the tip of the braid-reinforced guiding catheter was positioned in the inominate or proximal common carotid, and could not normally be advanced any further in the vasculature.

6. In my experience, an unreinforced sheath, or a braid reinforced guiding catheter, could not normally be introduced through tortuous anatomy such as the path from the aortic arch into the inominate artery and into the distal right common carotid artery. This is likely due to the fact, that unlike a coil, a braid does not have sufficient flexibility and kink-resistance to traverse the small radius bends encountered along this path.

7. In my experience, the aforementioned coil-reinforced sheath is superior to a braid-reinforced sheath and to an unreinforced sheath, because the coil-reinforced sheath has sufficient flexibility and kink resistance to traverse the tight curvature of challenging vasculature, such as the bends from the aortic arch into the inominate artery and into the distal right common carotid, with little or no difficulty in most patients. As a result, the coil-reinforced sheath enables a physician to treat conditions that may arise in difficult-to-reach areas of the vasculature utilizing guiding sheath and wire guide technology, that otherwise would require much more invasive techniques, or could not be preformed at all.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed by me on May 19, 2005, at Bloomington, IN.

Gary Roubin, M.D.

CURRICULUM VITAE

GARY SIDNEY SAMUEL ROUBIN

Contact Information:

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Date and Place of Birth:

April 25, 1948
Brisbane, Queensland, Australia

Marital Status:

Married—Peta Louise Roubin

Children:		
	Sidney	01/08/1998
	Jack	12/15/1998
	Sam	12/19/2001
	Joshua	02/04/2003

Education:

1970, B.V. Sc(Hons) (Bachelor of Veterinary Science) University of Queensland, Australia

1975, M.B., B.S. (Bachelor of Medicine, Bachelor of Surgery) University of Queensland, Australia

1985, Ph.D., University of Sydney, Australia
(Doctorate: "The hemodynamic and metabolic basis of impaired exercise tolerance in heart disease")

1995 M.D. University of Queensland, Australia. Studies Into the Development of Coronary Artery Stenting.

Other Qualifications

ECFMG	1975	#252-397-5
VQE	1977	
FLEX	1986	

Other Qualifications and Memberships

Fellow of the Royal Australian College of Physicians 1981 (F.R.A.C.P.)

Fellow of the American College of Cardiology 1986 (F.A.C.C.)

Fellow, Council on Clinical Cardiology, American Heart Association 1989

Fellow, Society for Cardiac Angiography and Intervention 1998

Fellow, Society for Vascular Medicine and Biology

Fellow, International Society of Endovascular Specialists

Member, Cardiac Society of Australia and New Zealand 1982

Associate Member, Society of Cardiovascular and Interventional Radiology

Member, American Medical Association 1986

Member, International Society for Endovascular Surgery 1995

Editorial Boards

Catheterization and Cardiovascular Diagnosis
Journal of Invasive Cardiology
Cardiovascular Interventions
Journal of Endovascular Therapy
Frequent Reviewer Circulation, American Journal of Cardiology

Medical Licenses

New South Wales, Australia (No. 21865), 1976

Georgia (No. 28694), 1986

District of Columbia (No. 18119) 1989

Alabama (No. N14986), 1989

New York (No. 207838), 1997

Utah (5338651-1205), 2003

Wyoming (6939A), 2004

PROFESSIONAL EXPERIENCE

1976-77	Resident Medical Officer, Royal Prince Alfred Hospital, Sydney, Australia
1977-78	Senior Resident Medical Officer, Royal Prince Alfred Hospital, Sydney, Australia
1978-79	Medical Registrar, Royal Prince Alfred Hospital, Sydney, Australia
1979-81	Cardiology Registrar, Hallstrom Institute of Cardiology, Sydney, Australia
1981-83	National Heart Foundation of Australia Postgraduate Medical Research Scholar, Department of Medicine, University of Sydney, Australia
1983-84	Lecturer, Department of Medicine, University of Sydney, Sydney, Australia Honorary Associate Cardiologist, Hallstrom Institute of Cardiology, Sydney, Australia Consultant Cardiologist, Queen Elizabeth II Rehabilitation Center, Sydney, Australia
1984-85	Research Associate, Department of Medicine (Interventional Cardiology), Emory University School of Medicine, Atlanta, Georgia
1985-86	Associate in Medicine (Interventional Cardiology) and Radiology,

	Andreas Gruentzig Cardiovascular Center, Emory University Hospital, Atlanta, Georgia
1986-89	Assistant Professor of Medicine (Interventional Cardiology) and Radiology, Andreas Gruentzig Cardiovascular Center, Emory University Hospital, Atlanta, Georgia
1986-89	Director of Research, Andreas Gruentzig Cardiovascular Center, Emory University School of Medicine, Emory University Hospital, Atlanta, Georgia
1989 - 1993	Associate Professor of Medicine, Director of Interventional Cardiology and Adult Cardiac Catheterization Laboratories, University of Alabama at Birmingham, Birmingham, Alabama
1993 - 1997	Professor of Medicine and Radiology, Director of Interventional Cardiology and Adult Cardiac Catheterization Laboratories, University of Alabama at Birmingham, Birmingham, Alabama
1997-5/30/2003	Chief, Endovascular Services, Lenox Hill Heart and Vascular Institute of New York, Lenox Hill Hospital, New York, New York; Clinical Professor of Medicine, New York University School of Medicine, New York, New York
9/2003-7/2004	Director of Neurovascular Interventions Utah Heart Clinic LDS Hospital 324 10th Street Salt Lake City, Utah
8/2004--	Chairman, Department of Interventional Cardiac & Vascular Services Lenox Hill Heart and Vascular Institute of New York Lenox Hill Hospital, New York, New York Clinical Professor of Medicine, New York University School of Medicine, New York, New York

Major Research Grants

1987-89	Co-Principal Investigator NHLBI/RO/HL33965-01A1. Emory Angioplasty versus Surgery Trial (E.A.S.T.). Comparison of PTCA and CABG in Patients with Multivessel Disease-A Prospective Randomized Trial
1989-90	Co-Investigator, Multicenter Bypass vs. Angioplasty Revascularization Interventive (BARI) Trial.
1998-present	Co-Principal Investigator, NINDS – Carotid Revascularization Endarterectomy vs. Stent (CREST) Trial.

Awards

Commonwealth University Scholarship - 1965
National Heart Foundation of Australia-Postgraduate Medical Research Scholarship - 1981
National Heart Foundation of Australia-Postgraduate Medical Research Scholarship - 1982
National Heart Foundation of Australia-Overseas Research Fellowship - 1984
National Heart Foundation of Australia-Overseas Research Fellowship – 1985
Royal Australian College of Physicians
Sir Thomas Greenaway Memorial Lecture 1990
Erasmus Thoraxcenter Interventional Cardiology "ETHICA" Award – 1996: Carotid Artery Stenting.

Listed "Best Doctors in America" Cardiovascular Diseases & Cardiac Catheterization & Interventional Cardiology in The Best Doctors in America 1992-2003 Woodward & White, publishers.

Consultant Committees

Special Review Committee - RFP NHLBI-HC-86-08 Applications of a Post CABG Study Coordinating Center
Special Review Committee - RFA NIH-86-HL-21-H Applications for BARI Data Coordinating Center
Clinical Council Representative on AHA
Scientific Program Committee 1990-1992
AHA-American Heart Association, Stroke Committee 1998-2001
ACC-American College of Cardiology-Peripheral Vascular Disease Committee 1998-2001

Publications

1. Clark L, **Roubin GS**: Cryptococcosis in a cat. Aust Vet J 46(11):544-8, 1970.

2. **Roubin GS**, Harris PJ, Eckhardt I, Hensley W, Kelly DT: Intravenous nitroglycerin in refractory unstable angina pectoris. Aust NZ J Med 12(6):598-602, 1982.

3. **Roubin GS**, Harris PJ, Bernstein L, Kelly DT: Coronary anatomy and prognosis after myocardial infarction in patients 60 years of age and younger. Circulation 67(4):743-9, 1983.

4. **Roubin GS**, Shen WF, Kelly DT, Harris PJ: The QRS scoring system for estimating myocardial infarct size: clinical, angiographic and prognostic correlations. J Am Coll Cardiol 2(1):38-44, 1983.

5. Harris PJ, **Roubin GS**, Sadick N, Choong CYP, Bautovich G, Kelly DT: The effect of high dose intravenous nitroglycerin on cardiovascular hemodynamic features and left ventricular function at rest and during exercise in patients with exertional angina. Am J Cardiol 52(2):113A-118A, 1983.

6. Abraham RD, **Roubin GS**, Harris PJ, Bernstein L, Kelly DT: Coronary and left ventricular angiographic anatomy and prognosis of survivors of first acute myocardial infarction. Am J Cardiol 52(3):257-260, 1983.

7. Nicholson MR, **Roubin GS**, Bernstein L, Harris PJ, Kelly DT: Prognosis after an initial non-Q wave myocardial infarction related to coronary arterial anatomy. Am J Cardiol 52(5):462-5, 1983.

8. Dunn RF, Newman HN, Bernstein L, Harris PJ, **Roubin GS,** Morris J, Kelly DT: The clinical features of isolated left circumflex coronary artery disease. Circulation 69(3):477-81, 1984.

9. **Roubin GS**, Choong CYP, Devinish-Meares S, Sadick NN, Fletcher PJ, Kelly DT: Beta-adrenergic stimulation of the failing ventricle: a double blind randomized trial of sustained oral therapy with prenalterol. Circulation 69(5):955-962, 1984.

10. **Roubin GS**, Shen WF, Nicholson M, Dunn RF, Kelly DT, Harris PJ: Anterolateral ST segment depression in acute inferior myocardial infarction - angiographic and clinical implications. Am Heart J 107(6):1177-1182, 1984.

11. Sadick NN, **Roubin GS**, Harris PJ, Hiroe M, Meares S, Bautovich G, Kelly DT: Effects of intravenous verapamil on the haemodynamic response to exercise in patients with angina pectoris. Acta Med Scand [Suppl] 682:92-8, 1984.

12. Shen WF, **Roubin GS**, Hirasawa K, Uren RF, Hutton BF, Harris PJ, Kelly DT:

regurgitation: beneficial effects of nifedipine. Am J Cardiol 54(6):605-9, 1984.

13. Shen WF, **Roubin GS**, Hirasawa K, Uren RF, Hutton BF, Harris PJ, Fletcher PJ, Kelly DT: Noninvasive assessment of acute effects of nifedipine on hemodynamics and cardiac function in patients with aortic regurgitation. J Am Coll Cardiol 4(5):902-7, 1984.

14. Shen WF, **Roubin GS**, Choong CY, Hutton BF, Harris PJ, Fletcher PJ, Kelly DT: Evaluation of relationship between myocardial contractile state and left ventricular function in patients with aortic regurgitation. Circulation 71(1):31-38, 1985.

15. Shen WF, **Roubin GS**, Fletcher PJ, Choong CY, Hutton BF, Harris PJ, Kelly DT: Effects of upright and supine position on cardiac rest and exercise response in aortic regurgitation. Am J Cardiol 55(4):428-431, 1985.

16. Choong CY, **Roubin GS**, Shen WF, Harris PJ, Kelly DT: Effects of nifedipine on systemic and regional oxygen transport and metabolism at rest and during exercise. Circulation 71(4):787-796, 1985.

17. Shen WF, **Roubin GS**, Hirasawa K, Choong CY, Hutton BF, Harris PJ, Fletcher PJ, Kelley DT: Left ventricular volume and ejection fraction response to exercise in chronic congestive heart failure: difference between dilated cardiomyopathy and previous myocardial infarction. Am J Cardiol 55(8):1027-31, 1985.

18. Choong CY, **Roubin GS**, Shen WF, Tokuyasu Y, Harris PJ, Kelly DT: Improvement in exercise capacity and associated changes in hemodynamics and left ventricular function after the addition of metoprolol to nifedipine in patients with stable exertional angina. Clin Cardiol 8(4):213-224, 1985.

19. Shen WF, **Roubin GS**, Uren RF, Hutton BF, Choong CY, Harris PJ, Fletcher PJ, Kelly DT: Radionuclide determination of right and left ventricular stroke volumes. Eur J Nucl Med 10(5-6):208-13, 1985.

20. Shen WF, Fletcher PJ, **Roubin GS**, Choong CY, Hutton B, Harris PJ, Kelly DT: Comparison of effects of isometric and supine bicycle exercise in patients with aortic regurgitation and normal ejection fraction at rest. Am Heart J 109(6):1300-5, 1985.

21. Leimgruber PP, **Roubin GS**, Anderson HV, Bredlau CE, Whitworth HB, Douglas JS Jr, King SB III, Gruentzig AR: Influence of intimal dissection on restenosis after successful coronary angioplasty. Circulation 72(3):530-535, 1985.

22. Bredlau CE, **Roubin GS**, Leimgruber PP, Douglas JS Jr, King SB III, Gruentzig AR: In-hospital morbidity and mortality in patients undergoing elective coronary angioplasty. Circulation 72(5):1044-1052, 1985.

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